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5.0	QUALITY SYSTEMS	5.0
5.1	SCOPE	5.1
5.1.a	This Standard sets out the general requirements that a laboratory h	5.1.1
5.1.b	This Standard includes additional requirements and information for	5.1.1 and 5.1.4
5.1.c	This Standard is for use by environmental testing laboratories in th	5.1.4
5.2	REFERENCES	5.2
5.3	DEFINITIONS	5.3
5.4	ORGANIZATION AND MANAGEMENT	5.4
5.4.1	Legal Definition of Laboratory	5.4.1.1 and 5.4.1.2
5.4.2	Organization	5.4.1.5
5.4.2.a	have managerial staff with the authority and resources needed to d	5.4.1.5.a
5.4.2.b	have processes to ensure that its personnel are free from any com	5.4.1.5.b
5.4.2.c	be organized in such a way that confidence in its independence of j	5.4.1.5.d
5.4.2.d	specify and document the responsibility, authority, and interrelation	5.4.1.5.f
5.4.2.d.1	a clear description of the lines of responsibility in the laboratory an	5.4.1.5.f
5.4.2.d.2	job descriptions for all positions.	5.5.2.4
5.4.2.e	provide supervision by persons familiar with the calibration or test	5.4.1.5.g
5.4.2.f	have a technical director(s) (however named) who has overall resp	5.4.1.5.h
5.4.2.g	have a quality assurance officer (however named) who has respon	5.4.1.5.i
5.4.2.g.1	serve as the focal point for QA/QC and be responsible for the over	5.4.1.5.i.1
5.4.2.g.2	have functions independent from laboratory operations for which th	5.4.1.5.i.2
5.4.2.g.3	be able to evaluate data objectively and perform assessments with	5.4.1.5.i.3
5.4.2.g.4	have documented training and/or experience in QA/QC procedures	5.4.1.5.i.4
5.4.2.g.5	have a general knowledge of the analytical test methods for which	5.4.1.5.i.5
5.4.2.g.6	arrange for or conduct internal audits as per 5.5.3 annually; and,	5.4.1.5.i.6
5.4.2.g.7	notify laboratory management of deficiencies in the quality system	5.4.1.5.i.7

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5.4.2.h	nominate deputies in case of absence of the technical director(s) a	5.4.1.5.j
5.4.2.i	have documented policy and procedures to ensure the protection o	5.4.1.5.c
5.4.2.j	for purposes of qualifying for and maintaining accreditation, each la	5.4.1.5.k
5.5	QUALITY SYSTEM - ESTABLISHMENT, AUDITS, ESSENTIAL Q	5.4.2
5.5.1	Establishment	5.4.2.1
5.5.1.a	The elements of this quality system shall be documented in the org	5.4.2.2
5.5.1.b	The quality documentation shall be available for use by the laborat	5.4.2.1
5.5.1.c	The quality documentation shall be available for use by the laborat	5.4.2.2.a
5.5.1.d	The laboratory management shall ensure that these policies and o	5.4.2.2.c and 5.4.2.2.d
5.5.1.e	The quality manual shall be maintained current under the responsib	5.4.2.5
5.5.2	Quality Manual	5.4.2.3
5.5.2.a	a quality policy statement, including objectives and commitments, b	5.4.2.3.a
5.5.2.b	the organization and management structure of the laboratory, its pl	5.4.2.3.b
5.5.2.c	the relationship between management, technical operations, suppo	5.4.2.3.c
5.5.2.d	procedures to ensure that all records required under this Chapter a	5.4.2.3.d
5.5.2.e	job descriptions of key staff and reference to the job descriptions of	5.4.2.3.e
5.5.2.f	identification of the laboratory's approved signatories; at a minimu	5.4.2.3.f
5.5.2.g	the laboratory's procedures for achieving traceability of measureme	5.4.2.3.g
5.5.2.h	a list of all test methods under which the laboratory performs its ac	5.4.2.3.h
5.5.2.i	mechanisms for ensuring that the laboratory reviews all new work t	5.4.2.3.i
5.5.2.j	reference to the calibration and/or verification test procedures used	5.4.2.3.j
5.5.2.k	procedures for handling submitted samples;	5.4.2.3.k
5.5.2.l	reference to the major equipment and reference measurement stan	5.4.2.3.l
5.5.2.m	reference to procedures for calibration, verification and maintenanc	5.4.2.3.m
5.5.2.n	reference to verification practices which may include interlaborator	5.4.2.3.n
5.5.2.o	procedures to be followed for feedback and corrective action when	5.4.2.3.o

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5.5.2.q	procedures for dealing with complaints;	5.4.2.3.q
5.5.2.r	procedures for protecting confidentiality (including national security	5.4.2.3.r
5.5.2.s	procedures for audits and data review;	5.4.2.3.s
5.5.2.t	processes/procedures for establishing that personnel are adequate	5.4.2.3.t
5.5.2.u	ethics policy statement developed by the laboratory and processes	5.4.2.3.u
5.5.2.v	reference to procedures for reporting analytical results; and,	5.4.2.3.v
5.5.2.w	a Table of Contents, and applicable lists of references and glossari	5.4.2.3.w
5.5.3	Audits, Reviews and Corrective Actions	5.4.13 and 5.4.14
5.5.3.1	Internal Audits	5.4.13.1 and 5.4.13.2
5.5.3.2	Managerial Review	5.4.14.1 and 5.4.14.2
5.5.3.3	Audit Review	5.4.13.3
5.5.3.4	Performance Audits	5.5.9.1
5.5.3.4.a	internal quality control procedures using statistical techniques; (see	5.5.9.1
5.5.3.4.b	participation in proficiency testing or other interlaboratory comparis	5.5.9.1.b
5.5.3.4.c	use of certified reference materials and/or in-house quality control	5.5.9.1.a
5.5.3.4.d	replicate testings using the same or different test methods;	5.5.9.1.c
5.5.3.4.e	re-testing of retained samples;	5.5.9.1.d
5.5.3.4.f	correlation of results for different but related analysis of a sample (f	5.5.9.1.e
5.5.3.5	Corrective Actions	5.4.10.6
5.5.3.5.a	In addition to providing acceptance criteria and specific protocols f	5.4.10.6.a
5.5.3.5.a.1	identify the individual(s) responsible for assessing each QC data ty	5.4.10.6.a.1
5.5.3.5.a.2	identify the individual(s) responsible for initiating and/or recommen	5.4.10.6.a.2
5.5.3.5.a.3	identify the individual(s) responsible for initiating and/or recommen	5.4.10.6.a.3
5.5.3.5.a.4	specify how out-of-control situations and subsequent corrective act	5.4.10.6.a.4
5.5.3.5.a.5	specify procedures for management (including the QA officer) to re	5.4.10.6.a.5

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5.5.3.5.b	To the extent possible, samples shall be reported only if all quality	5.4.10.6.b
5.5.4	Essential Quality Control Procedures	5.5.9.2
5.5.4.a	All laboratories shall have detailed written protocols in place to mo	5.5.9.2.a
5.5.4.a.1	Positive and negative controls to monitor tests such as blanks, spik	5.5.9.2.a.1
5.5.4.a.2	Tests to define the variability and/or repeatability of the laboratory r	5.5.9.2.a.2
5.5.4.a.3	Measures to assure the accuracy of the test method including calib	5.5.9.2.a.3
5.5.4.a.4	Measures to evaluate test method capability, such as detection limi	5.5.9.2.a.4
5.5.4.a.5	Selection of appropriate formulae to reduce raw data to final results	5.5.9.2.a.5
5.5.4.a.6	Selection and use of reagents and standards of appropriate quality;	5.5.9.2.a.6
5.5.4.a.7	Measures to assure the selectivity of the test for its intended purpo	5.5.9.2.a.7
5.5.4.a.8	Measures to assure constant and consistent test conditions (both i	5.5.9.2.a.8
5.5.4.b	All quality control measures shall be assessed and evaluated on a	5.5.9.2.b
5.5.4.c	The laboratory shall have procedures for the development of accep	5.5.9.2.c
5.5.4.d	The quality control protocols specified by the laboratory's method	5.5.9.2.d
5.6	PERSONNEL	5.5.2
5.6.1	General Requirements for Laboratory Staff	5.5.2.1
5.6.2	Laboratory Management Responsibilities	5.5.2.6
5.6.2.a	Defining the minimal level of qualification, experience and skills ne	5.5.2.6.a
5.6.2.b	Ensuring that all technical laboratory staff have demonstrated capa	5.5.2.6.b
5.6.2.c	Ensuring that the training of each member of the technical staff is k	5.5.2.6.c
5.6.2.c.1	Evidence must be on file that demonstrates that each employee ha	5.5.2.6.c.1
5.6.2.c.2	Training courses or workshops on specific equipment, analytical te	5.5.2.6.c.2
5.6.2.c.3	Training courses in ethical and legal responsibilities including the p	5.5.2.6.c.3
5.6.2.c.4	Analyst training shall be considered up to date if an employee traini	5.5.2.6.c.4
5.6.2.c.4.i	Acceptable performance of a blind sample (single blind to the analy	5.5.2.6.c.4.i
5.6.2.c.4.ii	Another demonstration of capability;	5.5.2.6.c.4.ii

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5.6.2.c.4.iii	Successful analysis of a blind performance sample on a similar test	5.5.2.6.c.4.iii
5.6.2.c.4.iv	At least four consecutive laboratory control samples with acceptabl	5.5.2.6.c.4.iv
5.6.2.c.4.v	If i-iv cannot be performed, analysis of authentic samples with resu	5.5.2.6.c.4.v
5.6.2.d	Documenting all analytical and operational activities of the laborato	5.5.2.6.d
5.6.2.e	Supervising all personnel employed by the laboratory;	5.5.2.6.e
5.6.2.f	Ensuring that all sample acceptance criteria (Section 5.11) are verif	5.5.2.6.f
5.6.2.g	Documenting the quality of all data reported by the laboratory; and	5.5.2.6.g
5.6.2.h	Developing a proactive program for prevention and detection of im	5.5.2.6.h
5.6.3	Records	5.5.2.5
5.7	PHYSICAL FACILITIES - ACCOMMODATION AND ENVIRONME	5.5.3
5.7.1	Environment	5.5.3.1
5.7.1.a	Laboratory accommodation, test areas, energy sources, lighting, h	5.5.3.1
5.7.1.b	The environment in which these activities are undertaken shall not i	5.5.3.1
5.7.1.c	The laboratory shall provide for the effective monitoring, control an	5.5.3.2
5.7.1.d	In instances where monitoring or control of any of the above menti	5.1.5 and 5.5.3.2
5.7.2	Work Areas	5.5.3.3
5.7.2.a	There shall be effective separation between neighboring areas whe	5.5.3.3
5.7.2.b	Access to and use of all areas affecting the quality of these activiti	5.5.3.4
5.7.2.c	Adequate measures shall be taken to ensure good housekeeping i	5.5.3.5
5.7.2.d	Work spaces must be available to ensure an unencumbered work	5.5.3.5
5.7.2.d.1	access and entryways to the laboratory;	5.5.3.5.a
5.7.2.d.2	sample receipt area(s);	5.5.3.5.b
5.7.2.d.3	sample storage area(s);	5.5.3.5.c
5.7.2.d.4	chemical and waste storage area(s); and,	5.5.3.5.d
5.7.2.d.5	data handling and storage area(s).	5.5.3.5.e
5.8	EQUIPMENT AND REFERENCE MATERIALS	5.5.5

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5.8.a	The laboratory shall be furnished with all items of equipment (inclu	5.5.5.1
5.8.b	All equipment shall be properly maintained, inspected and cleaned.	5.5.5.3
5.8.c	Any item of the equipment which has been subjected to overloadin	5.5.5.7
5.8.d	Each item of equipment including reference materials shall be label	5.5.6.4.c and 5.5.6.4.d and 5.5.5.8
5.8.e	Records shall be maintained of each major item of equipment and	5.5.5.5 and 5.5.5.5.g and 5.5.6.4.a
5.8.e.1	the name of the item of equipment;	5.5.5.5.a
5.8.e.2	the manufacturer's name, type identification, and serial number or	5.5.5.5.b
5.8.e.3	date received and date placed in service (if available);	5.5.5.5.i
5.8.e.4	current location, where appropriate;	5.5.5.5.d
5.8.e.5	if available, condition when received (e.g. new, used, reconditioned	5.5.5.5.j
5.8.e.6	copy of the manufacturer's instructions, where available;	5.5.5.5.e
5.8.e.7	dates and results of calibrations and/or verifications and date of the	5.5.5.5.f
5.8.e.8	details of maintenance carried out to date and planned for the futur	5.5.5.5.g
5.8.e.9	history of any damage, malfunction, modification or repair.	5.5.5.5.h
5.9	MEASUREMENT TRACEABILITY AND CALIBRATION	5.5.6
5.9.1	General Requirements	5.5.6.1
5.9.2	Traceability of Calibration	5.5.6.2.2.2 and 5.5.6.2.2.2.a, b, c
5.9.2.a	The overall program of calibration and/or verification and validation	5.5.6.2.2.a
5.9.2.b	Calibration certificates shall indicate the traceability to national stan	5.5.6.2.2.b
5.9.2.c	Where traceability to national standards of measurement is not app	5.5.6.2.2.c
5.9.3	Reference Standards	5.5.6.3
5.9.3.a	Reference standards of measurement held by the laboratory (such	5.5.6.3.1
5.9.3.b	There shall be a program of calibration and verification for referenc	5.5.6.3.1
5.9.3.c	Where relevant, reference standards and measuring and testing eq	5.5.6.3.2
5.9.4	Calibration	5.5.5.2
5.9.4.1	Support Equipment	5.5.5.2.1

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5.9.4.1.a	All support equipment shall be maintained in proper working order.	5.5.5.2.1.a
5.9.4.1.b	All support equipment shall be calibrated or verified at least annuall	5.5.5.2.1.b
5.9.4.1.b.1	The equipment shall be removed from service until repaired; or	5.5.5.2.1.b.1
5.9.4.1.b.2	The laboratory shall maintain records of established correction fact	5.5.5.2.1.b.2
5.9.4.1.c	Raw data records shall be retained to document equipment perfor	5.5.5.2.1.c
5.9.4.1.d	Prior to use on each working day, balances, ovens, refrigerators, fr	5.5.5.2.1.d
5.9.4.1.e	Mechanical volumetric dispensing devices including burettes (exce	5.5.5.2.1.e
5.9.4.1.f	For chemical tests the temperature, cycle time, and pressure of ea	5.5.5.2.1.f
5.9.4.1.g	For biological tests that employ autoclave sterilization see section	5.5.5.2.1.g
5.9.4.2	Instrument Calibration:	5.5.5.2.2
5.9.4.2.1	Initial Instrument Calibration:	5.5.5.2.2.1
5.9.4.2.1.a	The details of the initial instrument calibration procedures including	5.5.5.2.2.1.a
5.9.4.2.1.b	Sufficient raw data records must be retained to permit reconstructio	5.5.5.2.2.1.b
5.9.4.2.1.c	Sample results must be quantitated from the initial instrument calibr	5.5.5.2.2.1.c
5.9.4.2.1.d	All initial instrument calibrations must be verified with a standard ob	5.5.5.2.2.1.d
5.9.4.2.1.e	Criteria for the acceptance of an initial instrument calibration must	5.5.5.2.2.1.e
5.9.4.2.1.f	Results of samples not bracketed by initial instrument calibration st	5.5.5.2.2.1.f
5.9.4.2.1.g	If the initial instrument calibration results are outside established ac	5.5.5.2.2.1.g
5.9.4.2.1.h	Calibration standards must include concentrations at or below the r	5.5.5.2.2.1.h
5.9.4.2.1.i	If a reference or mandated method does not specify the number of	5.5.5.2.2.1.i
5.9.4.2.2	Continuing Instrument Calibration Verification	5.5.5.10
5.9.4.2.2.a	The details of the continuing instrument calibration procedure, calc	5.5.5.10.a
5.9.4.2.2.b	A continuing instrument calibration verification must be repeated at	5.5.5.10.b
5.9.4.2.2.c	Sufficient raw data records must be retained to permit reconstructio	5.5.5.10.c
5.9.4.2.2.d	Criteria for the acceptance of a continuing instrument calibration ve	5.5.5.10.d
5.9.4.2.2.e	If the continuing instrument calibration verification results obtained	5.5.5.10.e

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5.9.4.2.2.e.i	When the acceptance criteria for the continuing calibration verificati	5.5.5.10.e.i
5.9.4.2.2.e.ii	When the acceptance criteria for the continuing calibration verificati	5.5.5.10.e.ii
5.10	TEST METHODS AND STANDARD OPERATING PROCEDURES	5.5.4
5.10.1	Methods Documentation	5.5.4.1
5.10.1.a	The laboratory shall have documented instructions on the use and	5.5.4.1
5.10.1.b	All instructions, standards, manuals and reference data relevant to	5.5.4.1
5.10.1.1	Standard Operating Procedures (SOPs)	5.5.4.1.1
5.10.1.1.a	These documents, for example, may be equipment manuals provid	5.5.4.1.1.a
5.10.1.1.b	The test methods may be copies of published methods as long as	5.5.4.1.1.b
5.10.1.1.c	Copies of all SOPs shall be accessible to all personnel.	5.5.4.1.1.c
5.10.1.1.d	The SOPs shall be organized .	5.5.4.1.1.d
5.10.1.1.e	Each SOP shall clearly indicate the effective date of the document,	5.5.4.1.1.e
5.10.1.2	Laboratory Method Manual(s)	5.5.4.1.2
5.10.1.2.a	The laboratory shall have and maintain an in-house methods manu	5.5.4.1.2.a
5.10.1.2.b	This manual may consist of copies of published or referenced test	5.5.4.1.2.b
5.10.1.2.b.1	identification of the test method;	5.5.4.1.2.b.1
5.10.1.2.b.2	applicable matrix or matrices;	5.5.4.1.2.b.2
5.10.1.2.b.3	detection limit;	5.5.4.1.2.b.3
5.10.1.2.b.4	scope and application, including components to be analyzed;	5.5.4.1.2.b.4
5.10.1.2.b.5	summary of the test method;	5.5.4.1.2.b.5
5.10.1.2.b.6	definitions;	5.5.4.1.2.b.6
5.10.1.2.b.7	interferences;	5.5.4.1.2.b.7
5.10.1.2.b.8	safety;	5.5.4.1.2.b.8
5.10.1.2.b.9	equipment and supplies;	5.5.4.1.2.b.9
5.10.1.2.b.10	reagents and standards;	5.5.4.1.2.b.10
5.10.1.2.b.11	sample collection, preservation, shipment and storage;	5.5.4.1.2.b.11

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5.10.1.2.b.14	*procedure;*	5.5.4.1.2.b.14
5.10.1.2.b.15	*calculations;*	5.5.4.1.2.b.15
5.10.1.2.b.16	*method performance;*	5.5.4.1.2.b.16
5.10.1.2.b.17	*pollution prevention;*	5.5.4.1.2.b.17
5.10.1.2.b.18	*data assessment and acceptance criteria for quality control measur*	5.5.4.1.2.b.18
5.10.1.2.b.19	*corrective actions for out-of-control data;*	5.5.4.1.2.b.19
5.10.1.2.b.20	*contingencies for handling out-of-control or unacceptable data;*	5.5.4.1.2.b.20
5.10.1.2.b.21	*waste management;*	5.5.4.1.2.b.21
5.10.1.2.b.22	*references; and,*	5.5.4.1.2.b.22
5.10.1.2.b.23	*any tables, diagrams, flowcharts and validation data.*	5.5.4.1.2.b.23
5.10.2	*Test Methods*	5.5.4.2.1
5.10.2.a	*When the use of reference test methods for a sample analysis are*	5.5.4.2.1.a
5.10.2.b	*Where test methods are employed that are not required, as in the*	5.5.4.2.1.b
5.10.2.1	*Demonstration of Capability*	5.5.4.2.2
5.10.2.1.a	*Prior to acceptance and institution of any test method, satisfactory*	5.5.4.2.2.a
5.10.2.1.b	*Thereafter, continuing demonstration of method performance, as p*	5.5.4.2.2.b
5.10.2.1.c	*In cases where a laboratory analyzes samples using a test method*	5.5.4.2.2.c
5.10.2.1.d	*In all cases, the appropriate forms such as the Certification Statem*	5.5.4.2.2.d
5.10.2.1.e	*A demonstration of capability must be completed each time there is*	5.5.4.2.2.e
5.10.2.1.f	*In laboratories with a specialized "work cell(s)" (a group consisting*	5.5.4.2.2.f
5.10.2.1.g	*When a work cell(s) is employed, and the members of the cell chan*	5.5.4.2.2.g
5.10.2.1.h	*When a work cell(s) is employed the performance of the group mus*	5.5.4.2.2.h
5.10.3	*Sample Aliquots*	5.5.7.1
5.10.4	*Data Verification*	5.5.4.7.1

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5.10.4.a	The laboratory shall establish Standard Operating Procedure to en	5.5.4.7.1.a
5.10.4.b	The laboratory shall establish Standard Operating Procedures to e	5.5.4.7.1.b
5.10.4.c	The laboratory shall establish Standard Operating Procedures addr	5.5.4.7.1.c
5.10.5	Documentation and Labeling of Standards and Reagents	5.5.6.4
5.10.5.a	The laboratory shall retain records for all standards, reagents and	5.5.6.4.a
5.10.5.b	Original containers (such as provided by the manufacturer or vend	5.5.6.4.b
5.10.5.c	Records shall be maintained on reagent and standard preparation.	5.5.6.4.c
5.10.5.d	All containers of prepared reagents and standards must bear a uni	5.5.6.4.d
5.10.6	Computers and Electronic Data Related Requirements	5.5.4.7.2
5.10.6.a	all requirements of this Standard (i.e. Chapter 5) are met;	5.5.4.7.2
5.10.6.b	computer software is tested and documented to be adequate for us	5.5.4.7.2.a
5.10.6.c	procedures are established and implemented for protecting the inte	5.5.4.7.2.b
5.10.6.d	computer and automated equipment are maintained to ensure prop	5.5.4.7.2.c
5.10.6.e	it establishes and implements appropriate procedures for the maint	5.5.4.7.2.d
5.11	SAMPLE HANDLING, SAMPLE ACCEPTANCE POLICY AND SA	5.5.8
5.11.1	Sample Tracking	5.5.8.2
5.11.1.a	The laboratory shall have a documented system for uniquely identif	5.5.8.2.a
5.11.1.b	This laboratory code shall maintain an unequivocal link with the uni	5.5.8.2.b
5.11.1.c	The laboratory ID code shall be placed on the sample container as	5.5.8.2.c
5.11.1.d	The laboratory ID code shall be entered into the laboratory records	5.5.8.2.d
5.11.1.e	In cases where the sample collector and analyst are the same indiv	5.5.8.2.e
5.11.2	Sample Acceptance Policy	5.5.8.3.2
5.11.2.a	Proper, full, and complete documentation, which shall include sam	5.5.8.3.2.a
5.11.2.b	Proper sample labeling to include unique identification and a labeli	5.5.8.3.2.b
5.11.2.c	Use of appropriate sample containers;	5.5.8.3.2.c
5.11.2.d	Adherence to specified holding times;	5.5.8.3.2.d

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5.11.2.e	Adequate sample volume. Sufficient sample volume must be availa	5.5.8.3.2.e
5.11.2.f	Procedures to be used when samples show signs of damage, cont	5.5.8.3.2.f
5.11.3	Sample Receipt Protocols	5.5.8.3.1
5.11.3.a	Upon receipt, the condition of the sample, including any abnormaliti	5.5.8.3.1.a and 5.5.8.3
5.11.3.a.1	All samples which require thermal preservation shall be considered	5.5.8.3.1.a.1
5.11.3.a.2	The laboratory shall implement procedures for checking chemical p	5.5.8.3.1.a.2
5.11.3.b	The results of all checks shall be recorded.	5.5.8.3.1.b
5.11.3.c	Where there is any doubt as to the item's suitability for testing, whe	5.5.8.3.1.c
5.11.3.c.1	Retain correspondence and/or records of conversations concerning	5.5.8.3.1.c.1
5.11.3.c.2	Fully document any decision to proceed with the analysis of sampl	5.5.8.3.1.c.2
5.11.3.c.2.i	The condition of these samples shall, at a minimum, be noted on th	5.5.8.3.1.c.2.i
5.11.3.c.2.ii	The analysis data shall be appropriately "qualified" on the final repo	5.5.8.3.1.c.2.ii
5.11.3.d	The laboratory shall utilize a permanent chronological record such	5.5.8.3.1.d
5.11.3.d.1	This sample receipt log shall record the following:	5.5.8.3.1.d.1
5.11.3.d.1.i	Client/Project Name,	5.5.8.3.1.d.1.i
5.11.3.d.1.ii	Date and time of laboratory receipt,	5.5.8.3.1.d.1.ii
5.11.3.d.1.iii	Unique laboratory ID code (see 5.11.1), and,	5.5.8.3.1.d.1.iii
5.11.3.d.1.iv	Signature or initials of the person making the entries.	5.5.8.3.1.d.1.iv
5.11.3.d.2	During the log-in process, the following information must be unequi	5.5.8.3.1.d.2
5.11.3.d.2.i	The field ID code which identifies each container must be linked to	5.5.8.3.1.d.2.i
5.11.3.d.2.ii	The date and time of sample collection must be linked to the sampl	5.5.8.3.1.d.2.ii
5.11.3.d.2.iii	The requested analyses (including applicable approved test metho	5.5.8.3.1.d.2.iii
5.11.3.d.2.iv	Any comments resulting from inspection for sample rejection shall	5.5.8.3.1.d.2.iv
5.11.3.e	All documentation, such as memos or transmittal forms, that is tran	5.5.8.3.1.e
5.11.3.f	A complete chain of custody record form (Sections 5.12.3 and App	5.5.8.3.1.f
5.11.4	Storage Conditions	5.5.8.4

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5.11.4.a	Samples shall be stored according to the conditions specified by pr	5.5.8.4.a
5.11.4.a.1	Samples which require thermal preservation shall be stored under r	5.5.8.4.a.1
5.11.4.a.2	Samples shall be stored away from all standards, reagents, food a	5.5.8.4.a.2
5.11.4.b	Sample fractions, extracts, leachates and other sample preparation	5.5.8.4.b
5.11.4.c	Where a sample or portion of the sample is to be held secure (for e	5.5.8.4.b
5.11.5	Sample Disposal	5.5.8.4.c
5.12	RECORDS	5.4.12
5.12.1	Record Keeping System and Design	5.4.12.1.5
5.12.1.a	The records shall include the identity of personnel involved in samp	5.4.12.1.5.a
5.12.1.b	All information relating to the laboratory facilities equipment, analyti	5.4.12.1.5.b
5.12.1.c	The record keeping system shall facilitate the retrieval of all workin	5.4.12.1.5.c
5.12.1.d	All changes to records shall be signed or initialed by responsible st	5.4.12.1.5.d
5.12.1.e	All generated data except those that are generated by automated d	5.4.12.1.5.e
5.12.1.f	Entries in records shall not be obliterated by methods such as eras	5.4.12.1.5.f
5.12.1.g	Refer to 5.10.6 for Computer and Electronic Data.	5.4.12.1.5.g
5.12.2	Records Management and Storage	5.4.12.2.4
5.12.2.a	All records (including those pertaining to calibration and test equip	5.4.12.2.4.a
5.12.2.b	All records, including those specified in 5.12.3 shall be retained for	5.4.12.2.4.b
5.12.2.c	Records that are stored or generated by computers or personal co	5.4.12.2.4.c
5.12.2.d	The laboratory shall establish a record management system for co	5.4.12.2.4.d
5.12.2.e	Access to archived information shall be documented with an acces	5.4.12.2.4.e
5.12.2.f	The laboratory shall have a plan to ensure that the records are mai	5.4.12.2.4.f
5.12.3	Laboratory Sample Tracking	5.4.12.2.5
5.12.3.1	Sample Handling	5.4.12.2.5.1
5.12.3.1.a	Sample preservation including appropriateness of sample container	5.4.12.2.5.1.a
5.12.3.1.b	Sample identification, receipt, acceptance or rejection and log-in;	5.4.12.2.5.1.b

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5.12.3.1.c	Sample storage and tracking including shipping receipts, sample tr	5.4.12.2.5.1.c
5.12.3.1.d	The laboratory shall have documented procedures for the receipt a	5.4.12.2.5.1.d
5.12.3.2	Laboratory Support Activities	5.4.12.2.5.2
5.12.3.2.a	All original raw data, whether hard copy or electronic, for calibratio	5.4.12.2.5.2.a
5.12.3.2.b	A written description or reference to the specific test method used	5.4.12.2.5.2.b
5.12.3.2.c	Copies of final reports;	5.4.12.2.5.2.c
5.12.3.2.d	Archived standard operating procedures;	5.4.12.2.5.2.d
5.12.3.2.e	Correspondence relating to laboratory activities for a specific proje	5.4.12.2.5.2.e
5.12.3.2.f	All corrective action reports, audits and audit responses;	5.4.12.2.5.2.f
5.12.3.2.g	Proficiency test results and raw data; and,	5.4.12.2.5.2.g
5.12.3.2.h	Results of data review, verification, and cross-checking procedures	5.4.12.2.5.2.h
5.12.3.3	Analytical Records	5.4.12.2.5.3
5.12.3.3.a	Laboratory sample ID code;	5.4.12.2.5.3.a
5.12.3.3.b	Date of analysis and time of analysis is required if the holding time	5.4.12.2.5.3.b
5.12.3.3.c	Instrumentation identification and instrument operating conditions/p	5.4.12.2.5.3.c
5.12.3.3.d	Analysis type;	5.4.12.2.5.3.d
5.12.3.3.e	All manual calculations, e.g., manual integrations; and,	5.4.12.2.5.3.e
5.12.3.3.f	Analyst's or operator's initials/signature;	5.4.12.2.5.3.f
5.12.3.3.g	Sample preparation including cleanup, separation protocols, incuba	5.4.12.2.5.3.g
5.12.3.3.h	Sample analysis;	5.4.12.2.5.3.h
5.12.3.3.i	Standard and reagent origin, receipt, preparation, and use;	5.4.12.2.5.3.i
5.12.3.3.j	Calibration criteria, frequency and acceptance criteria;	5.4.12.2.5.3.j
5.12.3.3.k	Data and statistical calculations, review, confirmation, interpretatio	5.4.12.2.5.3.k
5.12.3.3.l	Quality control protocols and assessment;	5.4.12.2.5.3.l
5.12.3.3.m	Electronic data security, software documentation and verification, s	5.4.12.2.5.3.m
5.12.3.3.n	Method performance criteria including expected quality control requ	5.4.12.2.5.3.n

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5.12.3.4	Administrative Records	5.4.12.2.5.4
5.12.3.4.a	Personnel qualifications, experience and training records;	5.4.12.2.5.4.a
5.12.3.4.b	Records of demonstration of capability for each analyst; and	5.4.12.2.5.4.b
5.12.3.4.c	A log of names, initials and signatures for all individuals who are re	5.4.12.2.5.4.c
5.13	LABORATORY REPORT FORMAT AND CONTENTS	5.5.10.1
5.13.a	Except as discussed in 5.13.b, each report to an outside client shal	5.5.10.2
5.13.a.1	a title, e.g., "Test Report", or "Test Certificate", "Certificate of Resul	5.5.10.2.a
5.13.a.2	name and address of laboratory, and location where the test was c	5.5.10.2.b
5.13.a.3	unique identification of the certificate or report (such as serial numb	5.5.10.2.c
5.13.a.3.i	The total number of pages may be listed on the first page of the re	5.5.10.2.c.i
5.13.a.3.ii	Each page is identified with the unique report identification, the pag	5.5.10.2.c.ii
5.13.a.4	name and address of client, where appropriate and project name if	5.5.10.2.d
5.13.a.5	description and unambiguous identification of the tested sample inc	5.5.10.2.f
5.13.a.6	identification of test results derived from any sample that did not m	5.5.10.3.1.b
5.13.a.7	date of receipt of sample, date and time of sample collection, date(	5.5.10.2.g
5.13.a.8	identification of the test method used, or unambiguous description	5.5.10.2.e
5.13.a.9	if the laboratory collected the sample, reference to sampling proced	5.5.10.2.h
5.13.a.10	any deviations from (such as failed quality control), additions to or	5.5.10.3.1.a
5.13.a.11	measurements, examinations and derived results, supported by tab	5.5.10.2.i
5.13.a.12	when required, a statement of the estimated uncertainty of the test	5.5.10.3.1.c
5.13.a.13	a signature and title, or an equivalent electronic identification of the	5.5.10.2.j
5.13.a.14	at the laboratory's discretion, a statement to the effect that the resu	5.5.10.2.k
5.13.a.15	at the laboratory's discretion, a statement that the certificate or rep	5.5.10.2.l
5.13.a.16	clear identification of all test data provided by outside sources, suc	5.5.10.6
5.13.a.17	clear identification of numerical results with values outside of quant	5.5.10.3.1.f
5.13.b	Laboratories that are operated by a facility and whose sole function	5.5.10.1

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5.13.b.1	The in-house laboratory is itself responsible for preparing the regul	5.5.10.1.a
5.13.b.2	The laboratory provides information to another individual within the	5.5.10.1.b
5.13.c	Where the certificate or report contains results of tests performed b	5.5.10.6
5.13.d	After issuance of the report, the laboratory report shall remain unch	5.5.10.9
5.13.e	The laboratory shall notify clients promptly, in writing, of any event	5.4.13.2
5.13.f	The laboratory shall, where clients require transmission of test resu	5.5.10.7
5.13.g	Laboratories accredited to be in compliance with these standards s	5.5.10.2.m
5.14	SUBCONTRACTING ANALYTICAL SAMPLES	5.4.5
5.14.a	The laboratory shall advise the client in writing of its intention to su	5.4.5.2
5.14.b	Where a laboratory subcontracts any part of the testing covered un	5.4.5.1
5.14.c	The laboratory shall retain records demonstrating that the above re	5.4.5.4
5.15	OUTSIDE SUPPORT SERVICES AND SUPPLIES	5.4.6
5.15.a	Where the laboratory procures outside services and supplies, other	5.4.6.2
5.15.b	Where no independent assurance of the quality of outside support	5.4.6.2 and 5.4.6.4
5.15.c	The laboratory shall maintain records of all suppliers from whom it	5.4.6.3
5.16	COMPLAINTS	5.4.8